UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL No. 2804**
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	**Hon. Dan Aaron Polster**
The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al., Case No. 1:18-op-45459-DAP	)	

REPLY IN SUPPORT OF GENERIC MANUFACTURERS'
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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I. INTRODUCTION

Plaintiff's opposition (the "Opposition") confirms that all of Plaintiff's marketing-related claims against the Generic Manufacturers are based upon a failure-to-communicate or failure-to-warn theory—that the Generic Manufacturers should have affirmatively provided warnings beyond the labels of their generic medicines and corrected any false statements in the marketplace made by others.[1] But under well-settled decisions by the Supreme Court, the Sixth Circuit, and numerous other Circuit Courts—including *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014), *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013), and *Guarino v. Wyeth*, LLC, 719 F.3d 1245, 1249 (11th Cir. 2013)—these claims are preempted because of the "duty of sameness" imposed by federal law. In other words, federal law prohibits the Generic Manufacturers from issuing communications about their generic medicines to physicians or others that brand manufacturers never issued.

Plaintiff argues that the federal sameness requirement is somehow not applicable because the Generic Manufacturers could have unilaterally sent communications to physicians and others consistent with their medicines' labels. But the Sixth Circuit has expressly rejected this argument, recognizing that "[u]nder federal law, ***the [preemption] inquiry is whether the brand-name manufacturers sent out a warning***, not whether the proposed warning to be disseminated [by the

[1] The Generic Manufacturers are KVK-Tech, Inc. ("KVK"), Amneal Pharmaceuticals, Inc. ("API"), Watson Laboratories, Inc. ("Watson"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis"), Teva Pharmaceuticals, USA, Inc. ("Teva"), and Allergan Finance, LLC ("Allergan"). The claims against the Generic Manufacturers fail for the reasons set forth in the Manufacturers' Joint Motion to Dismiss ("Joint Motion") and Joint Reply ("Jointly Reply")—which the Generic Manufacturers incorporate herein by reference. But the claims against the Generic Manufacturers are particularly deficient for the reasons stated herein and their motion to dismiss. For purposes of this memorandum, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted.

generic manufacturer] contains substantially similar information as the label." *Darvocet*, 756 F.3d at 933 (quoting *Morris*, 713 F.3d at 777). Thus, by law, Generic Manufacturers could not make any warnings—unilateral or otherwise—about their generic medicines different than those made by brand manufacturers.[2]

Hoping to divert the Court's attention, Plaintiff largely ignores these controlling cases. Instead, Plaintiff devotes only a few pages to this critical issue and relies exclusively upon two decisions irrelevant to the claims pled here—*Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), and *Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150 (Cal. Ct. App. 2013). Both of these cases addressed an entirely different situation: a generic manufacturer's alleged failure to update its label for a generic medicine ***after*** the brand manufacturer changed the branded product's label. In those circumstances, the courts held that the "duty of sameness" does not prohibit the labeling change by the generic manufacturers. But Plaintiff does not and cannot allege that the FDA-approved labels for the Generic Manufacturers' opioid medicines differed from their brand equivalents in this case. In fact, Plaintiff does not allege any facts about the generic medicines sold by the Generic Manufacturers, much less the labeling history of any of those medicines. Under controlling law, Plaintiff's marketing-related claims fail.[3]

Attempting to avoid dismissal, the Opposition also argues in passing that Plaintiff has alleged false marketing by the Generic Manufacturers. But just like Plaintiff's First Amended Complaint ("FAC"), the Opposition fails to identify a single interaction between any Generic

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[2] Plaintiff does not dispute that Plaintiff's RICO Marketing Enterprise claim (Count I) fails if the state law marketing claims fail, as Generic Manufacturers cannot be penalized vis-à-vis a RICO claim for complying with the Food Drug & Cosmetic Act ("FDCA"). *See, e.g., Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014) (preemption analysis informs whether federal statute precludes claim under another federal statute).

[3] Because Plaintiff has only pled marketing-related claims against Teva and Allergan, the FAC should be dismissed in its entirety as to them on preemption grounds.

Manufacturer and any prescriber in Oklahoma (or elsewhere); a single false or purportedly misleading statement made by any Generic Manufacturer; or a single opioid prescription that was somehow written because of a false or misleading statement made by any Generic Manufacturer. Nor can it, because Generic Manufacturers "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis, PLC*, 787 F.3d 638 (2d Cir. 2015). At bottom, all marketing-related claims against the Generic Manufacturers must be dismissed.

Finally, Plaintiff's claims against KVK and API for failure to report suspicious orders or prevent diversion amount to improper attempts to enforce alleged violations of federal and state law for which no private right of action exists. In addition, Plaintiff does not identify a single allegation that KVK or API failed to report a suspicious order or that any suspicious order caused them harm. Under well-settled pleading standards, these claims should be dismissed, too.[4]

II. ARGUMENT

A. Plaintiff's Marketing Claims Against The Generic Manufacturers (Counts I, III, IV, V, VI, And X) Fail On Preemption Grounds.

Plaintiff concedes that its marketing claims against the Generic Manufacturers are based on a failure-to-communicate theory—that the Generic Manufacturers "failed to ensure that the warning language and other information was effectively communicated to physicians" (Pl's Opp.

[4] This reply brief also addresses the amici brief ("Amici Brief") submitted in opposition to the pending motions to dismiss (ECF No. 1026) and the Plaintiff's frivolous argument that Generic Manufacturers are somehow not allowed to incorporate other arguments by reference, despite this Court's case management order permitting them to do so. Neither the Amici Brief nor Plaintiff's argument changes the outcome—all claims against the Generic Manufacturers should be dismissed.

to Mot. To Dismiss ("Opp."), ECF No. 1008, at 21), and that they should have provided additional communications to physicians about "the current FDA-approved warning" through "'Dear Doctor' letters or other communications" (Opp. at 22).[5] The Supreme Court, the Sixth Circuit, and other courts addressing similar failure-to-communicate claims, however, have held them preempted. (Generic Manufacturers' Motion to Dismiss ("GM MTD"), ECF No. 929, at 12-22).

The rule is straightforward: generic labeling—including its warnings and other safety-related information—must be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 564 U.S. at 612-13. Thus, there can be no failure to communicate various alleged risks by the Generic Manufacturers because the sameness requirement prohibits generic manufacturers from going beyond the warnings of their branded counterparts. For this reason, the Supreme Court in *Mensing* held that the generic manufacturer could not unilaterally provide additional warnings through "Dear Doctor" letters to physicians[6] without violating the sameness requirement because "if generic manufacturers, but not the brand-name manufacturers, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* at 615; *see also Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1287-88 (10th Cir. 2013) (applying sameness requirement to hold claims against generic manufacturer under Oklahoma law preempted); *Kious v. Teva Pharm. USA, Inc.*, No. CIV-16-990-R, 2016 WL 9559038, at *3, 6 (W.D. Okla. Dec. 8, 2016) (holding same as to claims for fraud, negligent

[5] *See also id.* at 18-19; FAC ¶ 158 (alleging Generic Manufacturers failed to send "doctors and healthcare providers letters . . . which highlighted and explained the products' warnings, labeling, and other information.").

[6] Manufacturers use "Dear Doctor" letters to notify health care providers about new or updated warnings regarding a drug. *See* 21 C.F.R. § 200.5 ("Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care.").

misrepresentation, negligent concealment, strict liability, and breach of warranty under Oklahoma law).

Darvocet is squarely on point. There, the Sixth Circuit affirmed the dismissal of claims based upon the precise theory alleged here—that generic manufacturers should have sent "Dear Doctor" letters or other communications to healthcare professionals regarding the risks of their generic medicines even though the brand manufacturers did ***not*** send such communications. *Darvocet*, 756 F.3d at 932. The Sixth Circuit held that, under *Mensing*, requiring these unilateral communications would "violate the duty of sameness." *Id*. at 933. Agreeing with the other Circuit Courts to consider this issue, the Sixth Circuit emphasized that "[u]nder federal law, ***the [preemption] inquiry is whether the brand-name manufacturers sent out a warning***, not whether the proposed warning to be disseminated [by the generic manufacturer] contains substantially similar information as the label." *Id.* (collecting cases). Thus, "[b]ecause no brand-name manufacturer sent a warning . . . the generic manufacturers were not at liberty to do so." *Id.; see Morris*, 713 F.3d at 777 (applying rule to dismiss similar failure-to-communicate claims based upon alleged failure of generic manufacturer to send unilateral communications about content of current label); *Guarino*, 719 F.3d at 1249 (same).

Just as in *Darvocet*, the Generic Manufacturers could not have unilaterally sent any additional communications or warnings regarding their generic opioids because no brand-name manufacturers did so. Preemption does not rest upon the proposed content of any additional warning that generic manufacturers purportedly should have sent but, instead, on whether the brand manufacturers previously sent such a warning—which did not happen here. Plaintiff ignores the law and instead relies primarily upon *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013); (Opp. 21-22). That case is entirely inapposite. In *Fulgenzi*, the generic manufacturer allegedly

failed for years to update the label of its generic medicine to match that of the branded label, as required by federal law. The Sixth Circuit found no preemption to the extent plaintiff was arguing the inadequacy of the generic manufacturer's warning because plaintiff specifically alleged that the label "did not include the language contained in the updated Reglan label from 2004." *Id.* at 584; *see also id.* at 588.[7] Indeed, the Sixth Circuit and other sister Circuits have reaffirmed that *Fulgenzi* is limited to state law claims that are based upon a failure to update a generic medicine's label after a change to the label of the brand equivalent. *See Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 399 (6th Cir. 2013) (recognizing *Fulgenzi* applies to failure to update or "conform" claims, yet affirming dismissal of such claims for failure to plead sufficient facts); *Guarino*, 719 F.3d at 1250 ("In the present case, Guarino does not allege that Teva failed to update its label once the Brand Manufacturers strengthened it, so *Fulgenzi* is inapplicable.").

Here, however, Plaintiff does not and cannot allege that the Generic Manufacturers failed to update their product labels after a change in the FDA-approved labels of their brand equivalents. Nor does Plaintiff allege that the actual labels for the generic medicines differed from their brand equivalents at any point in time. In fact, Plaintiff does not even identify a single generic medicine sold by any of the Generic Manufacturers, much less the labeling history of those medicines.[8]

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[7] The *Fulgenzi* court also made clear that claims against a "generic-drug manufacturer whose branded counterpart had not updated its warning [in its FDA-approved label] . . . would be preempted under an impossibility theory" under *Mensing*. *Fulgenzi*, 711 F.3d at 587. Thus, to the extent Plaintiff now claims that the Generic Manufacturers should have unilaterally updated any warnings, *Fulgenzi* precludes that theory of liability.

[8] In fact, in *Strayhorn*, the Sixth Circuit affirmed the dismissal of a complaint that actually made allegations in support of a failure-to-conform claim, including that "several" of the Generic Manufacturers "fail[ed] to include information present in the label for the RLD and fail[ed] to implement changes to their own labels," and that some generic manufacturers "waited years to conform their labels to the RLD label." *Id.* at 399. But even those allegations were held insufficient under *Iqbal* and *Twombly*. Clearly, Plaintiff here has not pled such a claim since there are no allegations whatsoever to support such a theory.

The only other decision upon which Plaintiff relies—*Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150 (Cal. Ct. App. 2013)—is also a (non-binding) failure-to-update case and, thus, has no bearing on the issues presented here. In that case, the plaintiff alleged that the brand-name drug label for Fosamax was updated, but that the manufacturers of the generic equivalent failed to update their products' labels accordingly such that the generic drug label did not match the brand-name drug label. *Id*. at 152-53. The California Court of Appeal held that these claims were not preempted by federal law because, given the particularized allegations, it was possible for the generic manufacturers to comply both with the federal sameness requirement (*i.e.*, their federal duty to update the labels to match the branded label) and their state law duties. *Id*. at 157-58 (holding that it was possible for generic manufacturers to "comply with both a federal duty to make their labels match the Fosamax label . . . and a state tort law duty"); *id.* at 162 (noting that generic manufacturers could provide update to "health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes").

Not so here. Again, Plaintiff does not allege any failure by the Generic Manufacturers to communicate ***a label change*** to any branded opioid medicine—but asserts that the Generic Manufacturers unilaterally should have sent doctors and health providers additional "letters" that "highlighted and explained the products' warnings, labels, and other information." (FAC ¶ 158). Yet under *Mensing*, *Darvocet*, *Morris*, *Guarino*, and their progeny, Generic Manufacturers were not permitted to send the very communications sought by Plaintiff ***unless*** brand manufacturers had already done so—and Plaintiff does not allege anywhere in the FAC that any brand manufacturers had done so. *See, e.g., Darvocet*, 756 F.3d at 932 (recognizing that "[i]n *Mensing*, the Supreme Court held that generic manufacturers cannot send 'Dear Doctor' Letters unless their brand counterparts do so first"); *Guarino*, 719 F.3d at 1249 (affirming dismissal of claim that generic

manufacturer unilaterally failed to send communication about content of current label and holding that "[b]ecause the duty of sameness prohibits the generic manufacturers from taking such action ***unilaterally***, they are dependent on brand-names taking the lead").

Finally, Magistrate Judge Ruiz's Report and Recommendation (the "Report") in *Summit County* does not alter this conclusion. (ECF No. 1025, p. 49). Summit County did not assert any failure-to-communicate or failure-to-warn claims against the Generic Manufacturers. Thus, the Report did not address the preemption arguments and issues raised here.[9]

In short, controlling Sixth Circuit law holds that "claims [that] boil down to an alleged duty to provide additional information" for generic medicines are "essentially failure-to-warn claims that are preempted under *Mensing*." *Strayhorn*, 737 F.3d at 397. This controlling principle bars Plaintiff's state-law claims against Generic Manufacturers here.

B. Plaintiff's False Marketing Claims (Counts I, III, IV, V, VI, And X) Fail Because Plaintiff Does Not Allege Any False Marketing By The Generic Manufacturers, Much Less With The Specificity Required By Rule 9(b).

Plaintiff does not dispute the well-established principle that Generic Manufacturers refrain from marketing generic medicines because of drug substitution laws and the absence of any financial incentive to do so. (GM MTD, at 4-6, 8-12). It is no surprise, then, that the Opposition does not identify (1) a single statement attributable to any of the Generic Manufacturers about one

[9] For this reason and others, the cases cited in the Report do not help Plaintiff's claims here. For example, in *Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813 (S.D. Ohio 2013), the court found there was no preemption as to the fraudulent marketing claim, but held "[t]o the extent plaintiffs' claims rely on defendants' failure to warn consumers of the risks of amiodarone, they are preempted by the FDCA." *Id.* at 820. Likewise, *Beavers-Gabriel v. Medtronic, Inc.*, No. CIV 13-00686 JMS, 2015 WL 143944, at *6 (D. Haw. Jan 9, 2015) is entirely inapposite because the court addressed preemption in the context of the marketing of medical devices under an entirely separate statutory scheme. And in *Priest v. Sandoz, Inc.*, No. A-15-CV-00822-LY-ML, 2016 WL 11162903, at *7 (W.D. Tex. Dec. 29, 2016), *report and recommendation adopted,* 2016 WL 8896188 (W.D. Tex. Jan. 31, 2017), the court discussed preemption in the context of fraudulent marketing—not an alleged failure by a generic manufacturer to communicate information about its generic medicines.

of their medicines; (2) a single statement made by a Generic Manufacturer that reached an Oklahoma doctor, a tribal citizen who received an opioid prescription, or Plaintiff itself; or (3) any of the requisite details of any fraudulent conduct, such as who made an allegedly false statement, when, to whom, and why it is purportedly false. Given that Plaintiff does not allege any marketing by the Generic Manufacturers, it follows that Plaintiff cannot bring false marketing claims against them. *See Darvocet*, 756 F.3d at 932 (affirming dismissal of false marketing claims against all "Generic Manufacturers" because plaintiffs failed to plead specific facts against each defendant to support legal theory).

Nonetheless, Plaintiff argues it has satisfied its pleading burden and the particularity requirement under Rule 9(b) based on an omission theory—namely, that the Generic Manufacturers never corrected misstatements made by others or communicated additional warnings to physicians about their own medicines. (Opp. at 56-57, 148). But Plaintiff does not cite any authority to support the notion that a generic drug manufacturer has a legal duty to counter alleged misstatements and misrepresentations made by ***other*** manufacturers and unidentified third parties. Nor can it. Under Oklahoma law, such a duty to prevent or rectify the alleged conduct of others could apply only if there were a "special" relationship or "special" circumstances between the parties—none of which exist here. *See Thornton v. Ford Motor Co.*, 297 P.3d 413, 428 (Okla. Civ. App. 2012); *see also Darvocet*, 756 F.3d at 950 (applying principle to dismiss misrepresentation and other claims under Oklahoma law brought by consumer of generic medicine against brand manufacturer). More fundamentally, as described above, the Generic Manufacturers ***could not*** have done what Plaintiff argues they should have done with respect to their generic medicines, because of the federal sameness requirement.

But even if Plaintiff could somehow overcome these legal failures (and it cannot), Plaintiff fails to identify a single instance where a misstatement was made to a physician and where the Generic Manufacturers should have somehow intervened or acted, much less what they should have done. Plaintiff also ignores that, under well-settled law, Oklahoma doctors are legally obligated to be familiar with the actual labels of the medicines they prescribe—labels which Plaintiff concedes contain all of the necessary risk information for opioid medicines. *See McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982) (a physician has a "duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product."). This negates any omission claim.

In passing, Plaintiff disputes the Generic Manufacturers' argument that they do not promote their medicines, contending that it runs contrary to the allegations in the FAC.[10] (Opp. at 148). But the lone paragraph cited by Plaintiff (FAC ¶ 160) says no such thing. At most it is a conclusory allegation that fails to offer any facts (much less as to each Generic Manufacturer) and should be disregarded. *See Darvocet*, 756 F.3d at 932 (affirming dismissal of false marketing claims against all "Generic Manufacturers" because plaintiffs failed to plead specific facts against each defendant to support legal theory). Moreover, Plaintiff repeatedly asserts that its claims are

[10] Plaintiff's own allegations acknowledge that the decision to substitute a branded medicine for its generic equivalent is often made at the pharmacy level rather than by the prescribing physician. Specifically, Plaintiff alleges that when a patient is prescribed a "name-brand prescription opioid, a pharmacist may, with the doctor's or patient's consent, substitute a generic equivalent of the name-brand opioid in full accord with Oklahoma state law. O.A.C. 535:10-3-1.1(2). Many insurance companies will only pay for the generic equivalent, and so a patient often consents to the substitution of a generic equivalent for the name-brand drug. Consequently, even though the doctor may have prescribed a name-brand opioid, the prescription for that product often is filled with a generic equivalent by the pharmacist." (FAC ¶ 153). These allegations explain why generic manufacturers do not promote their medicines.

based upon a failure-to-communicate theory (Opp. at 56-57, 148), and fails to identify a single instance of promotion by any Generic Manufacturer about their generic medicines within Oklahoma or elsewhere. Because the Generic Manufacturers do not promote generic medicines and had no duty to correct—indeed, they could not have corrected—any alleged misstatements made by other manufacturers or third parties, Plaintiff's false marketing claims fail as a matter of law.

C. Plaintiff's Claims (Counts II, VII, VIII, And IX) Based Upon The Failure To Prevent Diversion Also Fail.[11]

The diversion claims against KVK and API fail for all the reasons discussed in Generic Manufacturers' Motion to Dismiss and the Joint Motion and Reply. (*See* GM MTD, at 21-23; Joint Motion, at Part I-V; Joint Reply, ECF No. 1089, at Part I, II, III, V)). In addition, Plaintiff's Opposition makes clear that the claims for failure to report suspicious orders or prevent diversion fail for additional reasons: (1) Plaintiff does not plead any facts supporting the contention that any Generic Manufacturer failed to report a suspicious order or that any suspicious order caused the Plaintiff any harm; and (2) they are misguided attempts to enforce violations of federal law for which no private cause of action exists.

Plaintiff does not dispute that in the allegations pertaining to Plaintiff's diversion theory (FAC ¶¶ 162-294), there is not a single factual allegation pled against any Generic Manufacturer. As such, the Opposition fails to identify a single suspicious order that any Generic Manufacturer allegedly failed to report; a single misleading statement or omission by any Generic Manufacturer regarding any federal or state diversion monitoring obligation (much less when they were made and to whom); or how any alleged failure to report by any Generic Manufacturer caused some

[11] Plaintiff's diversion claims are only asserted as KVK and API and not against the other Generic Manufacturers.

harm to any citizen of Plaintiff, as opposed to the actions of the many other independent actors that break the causal chain. This is woefully insufficient under federal pleading standards and does not support any claim against these Defendants. *See, e.g.*, *Strayhorn*, 737 F.3d at 400 (applying rule to affirm dismissal of claims); *Darvocet*, 756 F.3d at 931 (affirming dismissal of claims and rejecting conclusory allegations regarding wrongdoing and causation); *Ross v. Univ. of Tulsa*, No. 14-CV-484-TCK-PJC, 2015 WL 4064754, at *4 (N.D. Okla. July 2, 2015) (same). Indeed, it is clear from the FAC that the diversion claims are directed to the Pharmacy and Distributor Defendants—not any manufacturer of generic medicines. (FAC ¶¶ 200-262).

Plaintiff also argues that certain Generic Manufacturers made misstatements about preventing diversion. (Opp. at 148). Yet, the allegations in the FAC it cites to in its Opposition make no specific allegations that any Generic Manufacturer did any such thing and, instead, allege in conclusory fashion that "Distributor Defendants" or "Cardinal and Amerisource" had "a duty" or made certain "statements." (Opp. at 148 (citing FAC ¶¶ 208, 211)). The Opposition does not and cannot identify a single misstatement made by a single Generic Manufacturer—much less the details of any such statement, such as when it was made, where, to whom, and why. This alone is fatal to all of Plaintiff's claims.

Further, throughout its Opposition, Plaintiff does not dispute the paucity of its pleadings against KVK and API. Instead, Plaintiff attempts to assure the Court by reference to wholly conclusory allegations that there is no reason to delve into the sufficiency of the pleadings against these defendants because courts in other jurisdictions previously have denied motions to dismiss attacking the sufficiency of the pleadings. What Plaintiff does not mention is that neither KVK nor API has been a defendant in even one of those other cases. That other courts (in cases with different plaintiffs and different claims) found different allegations against different defendants

sufficient under different state pleading standards says nothing about whether Plaintiff has pled the plausible support required for its diversion claims against two ***generic*** manufacturers lumped in with unrelated distributors in this case as purported "Diversion Defendants."

Finally, Plaintiff argues that its diversion claims against certain Generic Manufacturers are not preempted because it is not bringing its claims "for failing to comply with their obligations under the Federal Controlled Substances Act ("FCSA")," but, rather, for "failing to comply with their state-law obligations to use due care in supplying dangerous opioid narcotics." (Opp. at 23-24). But Plaintiff ignores that there is no private cause of action to enforce the nebulous "state-law obligations" it seeks to rely upon,[12] and Plaintiff cannot circumvent that prohibition by dressing their claims as common law claims. Indeed, courts have rejected similar claims based on the alleged failure to report in accordance with federal and Oklahoma statutes or regulations that lack a private cause of action. *See, e.g., Pub. Serv. Co. of Okla. v. A Plus, Inc.*, No. CIV–10–651–D, 2011 WL 3329181, at *8 (W.D. Okla. Aug. 2, 2011) (applying rule); *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. Civ. App. 2000) (same). Likewise, the Sixth Circuit has held that permitting a plaintiff to enforce statutory or regulatory duties through common law negligence (and other common law claims) is improper because it "would, in effect, be permitting a private cause of

[12] Plaintiff also ignores its own Opposition, which continues to claim that KVK and API (and other so-called "Diversion Defendants") have failed to comply with their anti-diversion obligations under the FCSA. (Opp. at 95 (arguing that "violations of the Oklahoma CSA and FCSA constitute negligence per se")). There is no private right of action to enforce such obligations. *See McKesson Corp. v. Hembree*, No. 17-CV-323-TCK-FHM, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018) ("[C]ourts have rejected private attempts to enforce the [F]CSA through other vehicles."). And this theory conflicts with the exclusive enforcement authority of the federal government, including the DEA, over alleged violations of the FCSA; thus, the claims are impliedly preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-50 (2001); 21 U.S.C. §§ 875–883(granting federal government authority to investigate and enforce violations of FCSA).

action under" a statute or regulation that does not allow for one. *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994). Plaintiff should not be allowed to do so here.

In addition, as the Joint Reply makes clear, Plaintiff is not a member of the class protected by any Oklahoma anti-diversion statute or regulation. (Joint Reply, at Part II(F)(2)); *Raven Res., L.L.C. v. Legacy Bank*, 229 P.3d 1273, 1282 (Okla. App. 2009) (to recover for negligence per se under Oklahoma law, plaintiff must show, among other requirements, that he or she "is one of the class for whose special benefit the statute was enacted" and that "there is some indication of legislative intent, explicit or implicit, suggesting that the legislature wanted to create a private remedy"). In fact, Plaintiff makes no argument that the Oklahoma statutes and regulations it cites were designed to protect the Nation itself from economic injuries contingent upon harm to opioid users. (Joint Reply, at ¶ II(F)(2)). For this additional reason, Plaintiff's diversion-related claims should be dismissed.

D. The Amici Brief Offers No Support For The Legal Claims Against The Generic Manufacturers.

The Amici Brief in opposition to the Defendants' pending motions does not move the needle for Plaintiff. (ECF No. 1026). Although the Amici Brief purports to detail what the Amici believe to be the historical, political, legal and factual context for the "opioid epidemic" and its impact on various tribes, it is devoid of any legal arguments regarding the legal viability of the Plaintiff's claims against the Generic Manufacturers (or anyone else). It ignores the federal statutory and regulatory scheme imposing the sameness requirement on Generic Manufacturers and giving rise to federal preemption over all claims against the Generic Manufacturers. And nowhere in its discussion does the Amici Brief link any alleged conduct or resulting harm to any of the Generic Manufacturers, nor can it.

Because the Amici Brief makes no arguments as to any of the Generic Manufacturers and does not address the preemption and other arguments for dismissal raised by the Generic Manufacturers, the Amici Brief offers no basis to avoid dismissal of all claims against the Generic Manufacturers.

E. Plaintiff's Criticisms Of The Generic Manufacturers' Briefing Ignore this Court's Specific Directives.

At several points in its Opposition, Plaintiff takes issue with the Generic Manufacturers' incorporation of the Joint Motion filed by the Manufacturer Defendants and other briefing, including that submitted in the *Summit County* case. (*See* Opp. at 51-52; 74 n.190; 111 n.301). But Plaintiff ignores that this Court's Case Management Order One (CMO-1) specifically directed the parties to do so by providing for such incorporation by reference: "The parties shall endeavor to coordinate and consolidate briefing on all of the motions to dismiss and avoid duplicative briefing by incorporating similar arguments by reference." (ECF No. 232, at ¶ II(g)). Further, CMO-1 provided that no defendant would be held to waive an argument not raised in the initial Motions to Dismiss. (*Id.* at ¶ II(j)). Simply put, the Generic Manufacturers have complied with the Court's Order.

III. CONCLUSION

For all the reasons set forth above and in the Manufacturers' Joint Motion and Joint Reply, all claims against Generic Manufacturers should be dismissed with prejudice.

Dated: November 2, 2018

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the "litigation track" pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, L.R. 7.1(f), and the Court's July 26, 2018 Order.

Dated: November 2, 2018

By: /s/ *Steven A. Reed*
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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2018, a copy of the foregoing **Reply in Support of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint** was filed electronically in MDL Master Docket No. 17-md-2804 and in No. 1:18-op-45459-DAP. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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